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EXAMINER

HANDY, DWAYNE K

ART UNIT PAPER NUMBER

1743

4

DATE MAILED: 04/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

MF-4

Office Action Summary

Application No.
09/684,094

Applicant(s)
Weigl et al.

Examiner
Dwayne K. Handy

Art Unit
1743



-- Th MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-16 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

18) ☐ Interview Summary (PTO-413) Paper No(s) _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 16, applicant recites an inlet channel, an outlet channel, and a plurality of orifices, wherein the orifices provide a high static resistance than a single orifice but a substantially lower dynamic resistance to flow. This relationship of channels and orifices to provide the properties as stated in the claim is unclear to the Examiner. How are the orifices structurally related to the channels to provide the resistances described in the claim? Are they in the ceiling of the channel? The bottom? Clarification is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

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4. Claim 16 is rejected under 35 U.S.C. 102(e) as being anticipated by Kellogg et al. (6,143,248). Kellogg et al. teaches a microfluidic device which uses passive valves in conjunction with active and passive modes of transport to drive fluids through the channels of the device. In describing embodiments of their passive valves, Kellogg discloses the use of orifices surrounding the outlet channel of the device. "One means for controlling pressures necessary for flow are provided by textures in the surface material, such as concentric rings around the exit port: Such textures have increased resistance to flow along the surface relative to a smooth surface so that a fluid droplet may form with a 90° angle as described above in the case of a non-wetting solution..." (Col. 20, lines 5-12).

Inventorship

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipshutz et al. (5,856,174) in view of Parsons et al. (5,248,479). Lipshutz et al. recites a microfluidic device which contains channels and reservoirs for manipulating fluids for the purpose of performing analysis on the fluids in the channels and reservoirs (column 4, lines 4-45). The reference recites that the device may be used to filter materials (column 30, lines 15-28). "The filters may generally be within the apparatus, e.g., within the fluid passages leading from the sample preparation/extraction chamber. Lipshutz does not teach absorbent use as the driving means in a

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channel. Parsons et al. teach an agglutination reaction device (Figs 1-which uses a porous absorbent member (4) to draw fluid through a channel. Parsons also shows a triangular shaped area (7) which is also used to help draw fluid through the device. It would have been obvious to one of ordinary skill in the art to combine the teaching of absorbent fluid driving means in a channel with the device of Lipshutz. Lipshutz already teaches that absorbent may be used for filtration and that it may be in passages leading to and from chambers of the device. It would be obvious to use this absorbent as fluid driving means as taught by Parsons as well. This would allow for fluid control without external means providing the control.

9. Claims 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yager et al. (5,716,852) in view of Lipshutz et al. (5,948,684). Yager et al. (5,716,852). Yager et al. teach a microfabricated diffusion based sensor. The sensor is described best in column 3, lines 18-37 and includes a channel cell system in a substrate comprising a laminar flow channel, at least two inlet means in fluid connection with said laminar flow channel for respectively conducting into said laminar flow channel (1) an indicator stream...and (2) a sample stream. The laminar flow channel has depth sufficient enough to allow laminar flow of the streams adjacent to one another. The channel cell system may also include optical detection equipment for determining fluid properties in the laminar channel. Two embodiments of the channels of the device are shown in Figures 1 and 3 and described in columns 7-8. In describing operation of the device in column 7, Yager states that "...the sample containing small molecules of interest, sample stream 80, is

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brought into the device through sample stream inlet port (30), from whence it flows into sample stream channel (50), where it is referred to sample inlet stream (55). An indicator stream 70 is brought into indicator stream inlet port (20), from whence it flows into indicator stream inlet channel (40), where it is referred to as indicator inlet stream (45). Sample inlet stream (55) meets indicator inlet stream (45) at T-joint 58 at the beginning of flow channel 100, and the two streams flow in parallel laminar flow as indicator stream (70) and sample stream (80) to exit port (60)...Due to the low Reynolds number in the small flow channel 100, no turbulence-induced mixing occurs and the two streams flow parallel to each other without mixing.” The fact that the sample and indicator streams meet in the channel in parallel laminar flow means the fluid must have been in laminar flow upon exiting the entrance passageways (claims 5 and 6 recite a “smooth constant stream” or “smooth, continuous stream”). Also, Yager recites a plurality of viewing windows (140) for examining the contents of the flow channel. Yager et al. does not teach reservoirs in the surface of the device which contains the channels. Instead, Yager teaches input and output ports as well as injections for adding fluid to the device to be tested.

Lipshutz also teaches a microfluidic device for fluid assays. The device contains a microfluidic network for manipulation of fluids which has channels and reservoirs. For example, Lipshutz recites the use of chambers as storage reservoirs in column 19, lines 30-40. Specifically, Lipshutz recites element #412 as a waste reservoir. It would have been obvious to one of ordinary skill in the art to combine the reservoir teaching of Lipshutz with the device of Yager.

Providing reservoirs for reagent addition as well as for waste collection at the end of an analysis

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channel would remove the need for additional equipment to load and/or remove fluids from the testing device. In fact, the device could be provided as a self-contained diagnostic device which comes with reagents already loaded.

10. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yager et al. and Lipshutz et al. and further in view of Kellogg et al. (6,143,248). Yager et al. (5,716,852) and Lipshutz et al. (5,948,684), as combined above in paragraph 7 teach every element of claims 13 and 14 except for the use of surface tension valves. Kellogg et al. teaches the use of surface tension valves (wetable surfaces) in Figures 2A-3B and columns 17-20. Basically, Kellogg uses changes in interfacial energy to stop fluids at various locations in the device. This energy is overcome by a change in property at the valve site (passive transport) or by centripetal force (active transport). It would have been obvious to one of ordinary skill in the art to combine the passive transport valves with the combined teachings of Yager and Lipshutz. The use of passive transport as taught by Kellogg would allow for fluid control in the channels without additional or external fluid control elements.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Anderson et al. (5,992,591) is cited as containing many of the features of Lipshutz et al. Weigl et al. (5,948,684; 5,972,710; 6,136,272; 6,171,865), Yager (6,007,775; 6,277,641) and


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Forster et al. (5,974,867; 6,134,950) are all cited as further examples of devices used to determine concentration in a microfluidic laminar flow channel. Bjornson et al. (6,284,113) shows an apparatus for transferring liquids to a microfluidic device which includes wicking material in the injection channels.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (703)-305-0211. The examiner can normally be reached on Monday-Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703)-308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703)-772-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0661.


Jill Warden
Supervisory Patent Examiner
Technology Center 1700

dkh

March 26, 2002